

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Johan H. Geerke and
Steven F. Stone**

Confirmation No.: **1409**

Serial No.: **09/324,343**

Group Art Unit: **1617**

Filing Date: **June 2, 1999**

Examiner: **Chong, Yong Soo**

For: Methods And Apparatus For Determining Formulation Orientation Of Multi-Layered Pharmaceutical Dosage Forms

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**APPELLANT'S REPLY BRIEF
PURSUANT TO 37 C.F.R. § 41.41 AND M.P.E.P. § 1208**

Appellant submits this Reply Brief in response to the Examiner's Answer dated February 8, 2008 in connection with the above-identified application. This reply is being filed within two months of said Answer.

The Board's attention is drawn to the fact that although Appellant's Brief withdrew Claim 38 from the instant appeal, the Examiner's Answer list this claim among those finally rejected. Claim 38 therefore is *not* presently before the Board for review.

1. STATUS OF CLAIMS

Pending	:	Claims 1 to 38
Rejected	:	Claims 18-20, 32-33, 35-36, and 38
Objected to	:	Claims 34 and 37
Allowed	:	None
Withdrawn	:	Claims 1-17 and 21-31
Appealed	:	Claims 18-20, 32-33, and 35-36
Appeal Withdrawn	:	Claim 38.

2. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issue on appeal is as follows:

- Whether or not those of ordinary skill in the art would have found the inventions recited in claims 18-20, 32-33, and 35-36 to have been obvious over U.S. Pat. No. 5,248,310 to Barclay, *et al.* (“the Barclay patent”) in view of U.S. Pat. No. 5,785,994 to Wong, *et al.* (“the Wong patent”) in further view of U.S. Pat. No. 5,294,770 to Riddle, *et al.* (“the Riddle patent”).

3. ARGUMENTS

Not only does the Examiner's Answer fail to identify any objective evidence indicating that those of ordinary skill would have found it obvious to modify the teachings of the prior art in a way that would have produced a claimed invention, but it is clear from the Answer that the Examiner's rejection of the pending claims is based upon an incorrect reading of at least one of the applied references.

According to the Examiner, the claimed inventions would have been obvious because the Wong patent allegedly discloses a three-layer dosage form having multiple drug-containing layers. At pages 5-6 of the Answer, for example, the Examiner contends that the Wong patent teaches a "three or more layered tablet" in which a "varying pattern of drug release . . . is achieved by drug concentrations in each layer." The Examiner repeats virtually the same contention on page 9.

In neither instance, however, does the Examiner identify disclosure in the Wong patent that allegedly teaches "drug concentrations in each layer." Indeed, as Appellant noted in its opening brief, the Wong patent appears to disclose a dosage form containing only a *single* drug-containing layer (Appellant's Brief at page 4).

Accordingly, the Examiner's rejection of the pending claims for alleged obviousness lacks factual basis. For at least this reason, the instant patent application should be remanded to the Examiner with an instruction to withdraw the rejection.

Such an outcome is appropriate, notwithstanding the Examiner's allegation regarding the possibility of compressing the overcoat disclosed by the Wong patent:

Appellant has admitted to the fact that Wong teaches a three layer tablet as taught as element 14 in Figure[s] 2 and 4. Examiner respectfully reminds Appellant that nothing in the Wong references teaches that this particular composition comprising the overcoat cannot be compressed into a capsule-shaped tablet. This is merely Appellant making a conjecture based on no factual evidence or teaching from the Wong reference.

(Examiner's Answer at paragraph bridging pages 9 and 10). The Wong patent states that element 14 in Figures 2 and 4 comprises "an external coat 14 on the exterior surface of wall 12" (col. 4, lines 41-45), and does not teach or suggest that external coat 14 can comprise a layer that is compressed into a capsule-shaped osmotic tablet in accordance with independent

claims 18 and 20. Assuming *arguendo* that the Examiner is correct that “nothing in the Wong reference teaches that . . . the overcoat cannot be compressed into a capsule-shaped tablet”, such argument represents an improper attempt to shift the evidentiary burden under the legal concept of *prima facie* obviousness from the Examiner, who bears the initial burden of showing that it allegedly would be obvious to compress the overcoat into a capsule-shaped tablet, to the Appellant, on whom the evidentiary burden does not fall until the Examiner has made the requisite showing. *See In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993). Because the Examiner has not met this initial burden, Appellant is not obligated to provide the “factual evidence or teaching” demanded in the Examiner’s Answer at pages 9-10.

Respectfully submitted,

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